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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,597	08/27/2001	Frederick A. Gage	106996	2731

25944 7590 05/19/2004

OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER	
DAVIS, RUTH A	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,597	GAGE ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-20 and 44-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-20 and 44-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed February 19, 2004 has been received and entered into the case. Claims 4 and 21 – 43 are canceled; claims 44 – 63 are added; claims 1 – 3, 5 – 20 and 44 – 63 are pending and considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 45 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45 and 62 are rendered vague and indefinite for "from about 10 to about 30 or more Units" because it is unclear what the phrase is meant to encompass. It is unclear if the range is a limitation, or if the amount of thrombolytic agent is merely at least 10 units. It is also noted that the claims are substantial duplicates of each other.

Claims 48 and 63 are substantial duplicates of each other.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 5 – 6, 20, 44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Dow et al. (0407780 A2).

Applicant claims a method for treating an organ with a thrombolytic agent to promote thrombolysis, the method comprising perfusing the organ ex vivo, with a perfusion solution comprising a thrombolytic agent. The thrombolytic agent is selected from streptokinase, urokinase, alteplase, tenecteplase, tissues plasminogen activators, anistreptase, anisoylated streptokinase, reteplase, and mutant tissue plasminogen activators; specifically streptokinase. The organ is selected from a heart, liver, kidney, lung, pancreas and intestine, specifically kidney.

Dow teaches methods for preserving donor tissue transplants by administering an ex-vivo perfusion of active agents and streptokinase, wherein the tissue may be kidney, hearts, lungs or liver (p.3 line 21-35).

The reference anticipates the claimed subject matter.

5. Claims 1, 5, 9, 18 – 20, 44 – 46, 48, and 62 – 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchida et al. (JP 62067001 A).

Applicant claims a method for treating an organ with a thrombolytic agent to promote thrombolysis, the method comprising perfusing the organ ex vivo, with a perfusion solution comprising a thrombolytic agent. The organ is removed from a human; the thrombolytic agent is selected from streptokinase, urokinase, alteplase, tenecteplase, tissues plasminogen activators, anistreptase, anisoylated streptokinase, reteplase, and mutant tissue plasminogen activators. The thrombolytic agent is administered at 5000 –58,000,000 IU; about 10 – 30 more units; or about 10,000 IU. The organ is perfused for at least 4 hours, or 4 – 12 hours; and is selected from a heart, liver, kidney, lung, pancreas and intestine, specifically a kidney.

Uchida teaches a method for treating organs, particularly the kidney, comprising preserving the organ with 1000 – 10000 IU or plaminogen activator, or urokinase (abstract). The organ is preserved at 0 – 10C for 72 – 120 hours (abstract).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 3, 5 – 20 and 44 – 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yland in view of Uchida and Dow.

Applicant claims a method for treating an organ with a thrombolytic agent to promote thrombolysis, the method comprising perfusing the organ ex vivo, with a perfusion solution comprising a thrombolytic agent. The organ is removed from a human; the thrombolytic agent is selected from streptokinase, urokinase, alteplase, tenecteplase, tissues plasminogen activators, anistreptase, anisoylated streptokinase, reteplase, and mutant tissue plasminogen activators; specifically streptokinase. The thrombolytic agent is administered at 10,000 – 1,500,000 IU; 100,000 – 300,000 IU, 5000 –58,000,000 IU; about 250,000 IU; or about 10 – 30 more units. The perfusion solution further comprises a vasodilator. The organ is perfused for 1 – 20 hours, at least 4 hours, or 4 – 12 hours; and is selected from a heart, liver, kidney, lung, pancreas and intestine, specifically kidney. Applicant additionally claims the method wherein the solution is perfused with a perfusion circuit. Applicant finally claims the method wherein an organ is treated with a thrombolytic agent comprising connecting the organ to a perfusion circuit, prefusing with the agent, measuring a parameter indicating thrombolysis, and determining if thrombolysis occurs. The perfusion circuit has systolic pressure of less than 60, between 45 – 60 and about 50 mm Hg; the perfusion occurs at 2 – 10C, specifically 5C.

Yland teaches methods of preserving organs, specifically kidney, comprising perfusion of the organ (abstract). Specifically, that machine perfusion can be high or low flow at 6 – 9C. Yland teaches methods wherein kidneys are removed, high and low flow machine flushed (perfused) with active agents at 0 – 4C for about 72 hours (p.536, Materials and Methods). Perfusion pressures are 30 – 40 mm Hg with a controlled perfusion circuit (p.536, Equipment). Yland teaches that such methods better preserves the organ (p.539).

Yland does not teach the method wherein the active agent is streptokinase. However, Dow teaches methods for preserving donor tissue transplants by administering an ex-vivo perfusion of active agents and streptokinase, wherein the tissue may be kidney, hearts, lungs or liver (p.3 line 21-35), and Uchida teaches a method for treating organs, particularly the kidney, comprising preserving the organ with 1000 – 10000 IU or plaminogen activator, or urokinase (abstract). The organ is preserved at 0 – 10C for 72 – 120 hours (abstract). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use streptokinase in the methods of Yalnd because they were known in the art for their claimed purpose, as evidenced by the cited references.

The references do not teach the methods wherein the organ is human, with each claimed amounts of agent, times or pressures of perfusion. However, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the variables of the cited references with a reasonable expectation for successfully treating an organ with a perfusion solution.

Response to Arguments

Applicant argues that the references do not teach the organ is ex vivo, or where perfusion is with thrombolytic agents.

However, these arguments fail to persuade because the cited references specifically teach ex vivo perfusion with streptokinase, as stated in the rejections above.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
May 11, 2004.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER